

Screening Checklist

For all Premarket Notification 510(k) Submissions

Device Name:						K						
Submitter (Company):												
Items which should be included <i>(circle missing & needed information)</i>						SPECIAL		ABBREVIATED		TRADITIONAL		IF ITEM IS NEEDED AND IS MISSING
						YES	NO	YES	NO	YES	NO	
1. Cover Letter clearly identifies Submission as: a) "Special 510(k): Device Modification" b) "Abbreviated 510(k)" c) Traditional 510(k)						GO TO # 2,3		GO TO # 2,4,5		GO TO #2, 5		
2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS												IF ITEM IS NEEDED AND IS MISSING
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)						NA		YES		NO		AND IS MISSING
						SPECIALS		ABBREVIATED		TRADITIONAL		
						YES	NO	YES	NO	YES	NO	
a) trade name, classification name, establishment registration number, device class												
b) OR a statement that the device is not yet classified						FDA-may be a classification request; see coordinator						
c) identification of legally marketed equivalent device						NA						
d) compliance with Section 514 - performance standards						NA						
e) address of manufacturer												
f) Truthful and Accurate Statement												
g) Indications for Use enclosure												
h) SMDA Summary or Statement (FOR ALL DEVICE CLASSES)												
i) Class III Certification & Summary (FOR ALL CLASS III DEVICES)												
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals												
k) Proposed Labeling:												
i) package labeling (user info)												
ii) statement of intended use												
iii) advertisements or promotional materials												
i) MRI compatibility (if claimed)												
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:												
i) Labeling												
ii) intended use												
iii) physical characteristics												
iv) anatomical sites of use												
v) performance (bench, animal, clinical) testing						NA						
vi) safety characteristics						NA						
m) If kit, kit certification												
3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II , III OR RESERVED CLASS I DEVICE												
a) Name & 510(k) number of legally marketed (unmodified) predicate device												

b) STATEMENT - INTENDED USE AND INDICATIONS FOR USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*			* If no - STOP not a special	
c) STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED*			* If no - STOP not a special	
d) Design Control Activities Summary				
i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis				
ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied				
iii) A declaration of conformity with design controls. The declaration of conformity should include:				
1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met				
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review.				

	SPECIALS		ABBREVIATED		TRADITIONAL		IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE FILL OUT THE STANDARDS ABBREVIATED FORM ON THE H DRIVE							
a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							

ii) A specification, for each consensus standard, that all requirements were met, except for inapplicable requirements or deviations noted below			
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed			
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device			
v) A specification of any deviations from each applicable standard that were applied			
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference			
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations			
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards			

5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:							
i) component & material							
ii) identify patient-contacting materials							
iii) biocompatibility of final sterilized product							
b) Sterilization and expiration dating information:							
i) sterilization method							
ii) SAL							
iii) packaging							
iv) specify pyrogen free							
v) ETO residues							
vi) radiation dose							
c) Software validation & verification:							
i) hazard analysis							
ii) level of concern							
iii) development documentation							
iv) certification							

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening ____ Yes ____ No

Date: _____

Reviewer: _____

Concurrence by Review Branch: _____